K071081

510(k) SUMMARY

Zodiac DynaMo Semi-Rigid Spinal System
510(k) SUMMARY
July 2007

OCT 24 2007

Company: Alphatec Spine, Inc.
2051 Palomar Airport Road#100
Carlsbad, CA 92011 USA
Direct: (760) 494-6769
Fax: (760) 431-9132

Contact Person: Paula Morgan, Director of Regulatory Affairs & Compliance

Trade/Proprietary Name: Zodiac DynaMo Semi-Rigid Spinal System

Common Name: Pedicle Screw Spinal Device

Classification Name: Spinal Interlaminal Fixation Orthosis
Pedicle Screw Spinal System

Product Description:

The Zodiac DynaMo Semi-Rigid Spinal System is a top loading anterior/posterior spinal fixation system consisting of various types and sizes of implantable components that are assembled to create a rigid spinal construct.

Indications for Use:

It is intended that this device, in any system configuration be removed after development of solid fusion mass. Hook component indications are limited to T7-L5. Sacral screw indications are limited to the sacrum only.

1) The Zodiac DynaMo Semi-Rigid Spinal System when used as a hook and sacral screw fixation system (nonpedicle screw) is intended for:

   a. Patients having fractures of the thoracic and lumbar spine.
   b. Patients having deformity (i.e., idioscoliosis, neuromuscular scoliosis, or kyphoscoliosis with associated paralysis or spasticity).
   c. Patients having spondylolisthesis (i.e., isthmic spondylolisthesis, degenerative spondylolisthesis, and acute pars fracture allowing spondylolisthesis).

2) The Zodiac DynaMo Semi-Rigid Spinal System , when used as a pedicle screw system in the thoraco-lumbo-sacral region of the spine is intended for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

3) In addition, the Zodiac DynaMo Semi-Rigid Spinal System , when used as a pedicle screw fixation system is intended for:

a. Patients receiving only autogenous bone graft.
b. Patients having the device fixed or attached to the lumbar and sacral spine and having severe spondylolisthesis grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.

4) The Zodiac DynaMo Semi-Rigid Spinal System , when used as a laminar hook and bone screw system is intended for:

a. Patients having fractures of thoracic and lumbar spine.
b. Patients having thoracolumbar deformity (i.e., idioscoliosis, neuromuscular scoliosis, or kyphoscoliosis with associated paralysis or spasticity).
c. Patients having spondylolisthesis (i.e., isthmic spondylolisthesis, degenerative spondylolistheses and acute pars fracture allowing spondylolisthesis).

Substantial Equivalence:

The Zodiac DynaMo Semi-Rigid Spinal System is substantially equivalent to the following predicate devices:

Trade/Proprietary Name	Manufacturer	Clearance
Moss-Miami Spinal System	DePuy Spine, Inc.	K030383

Performance Data:

Mechanical and dynamic testing of the semi-rigid spinal fixation system was performed. The test results demonstrate that the mechanical performance of the Zodiac DynaMo Semi-Rigid Spinal System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2007

Alphatec Spine, Inc.
% Ms. Paula Morgan
Director of Regulatory Affairs & Compliance
2051 Palomar Airport Road, #100
Carlsbad, California 92011

Re: K072081
Trade/Device Name: Zodiac DynaMo Semi-Rigid Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: KWP, MNH, MNI
Dated: July 27, 2007
Received: July 30, 2007

Dear Ms. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072081

INDICATIONS FOR USE

510(k) Number (if known): TBD

Device Name: Zodiac DynaMo Semi-Rigid Spinal System

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Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number

Concurrence of CDRH, Office of Device Evaluation (ODE)

K072081

4) The Zodiac DynaMo Semi-Rigid Spinal System , when used as a laminar hook and bone screw system is intended for:

a. Patients having fractures of thoracic and lumbar spine.
b. Patients having thoracolumbar deformity (i.e., idioscoliosis, neuromuscular scoliosis, or kyphoscoliosis with associated paralysis or spasticity).
c. Patients having spondylolisthesis (i.e., isthmic spondylolisthesis, degenerative spondylolistheses and acute pars fracture allowing spondylolisthesis).

Mark A Milkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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